

### **REMARKS**

Claims 1 to 31 are currently pending in the application. Claims 1 to 31 have been rejected. In view of the above amendments and the following remarks, Applicants respectfully submit that this application is in condition for allowance. Accordingly, reconsideration and a timely notice of allowance are respectfully requested.

#### **Objection To The Abstract Of The Disclosure**

The Examiner objected to the abstract of the disclosure, because it exceeded the limit of less than 150 words. Applicants have amended the abstract to contain less than 150 words. The amendments consist of deletions of existing text and minor changes for clarity. No new matter has been added, full support for the amendments being found in the specification and drawings as filed. Entry of the amendments to the abstract is respectfully requested.

In view of the amendments to the abstract, Applicants respectfully submit that the Examiner objections have been obviated.

#### **Rejections Under 35 U.S.C. §102**

The Examiner rejected claims 1 to 31 under 35 U.S.C. §102(b) as being anticipated by Segal et al. (U.S. Patent No. 6,402,207). Applicants respectfully traverse this rejection.

Claim 1 recites where “said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues.” Applicants respectfully submit that Segal et al. fail to teach or suggest this limitation. As explained in the specification in paragraphs 78 to 80, the application affordance can comprise, for example, a shape suggestive of a human spine and rib cage for neuraxial uses; a bellows-like shape suggestive of air flow for respiratory applications; and a bulbous shape suggestive of a human colon for enteral applications.

Segal et al. disclose a connection system having converters with standard luer connections, and different interconnections. A key is provided in the form of surface features that prevent incorrect connections. The surface features may be geometric shapes, such as

triangles, squares, pentagons, hexagons, or other regular polygon or quadrilateral shape. See, col. 6, lines 43 to 47. “The identity of the connector type is readily recognizable by the skilled artisan from the shape or design of the mating surfaces, as well as from the distinctive markings on the outer surfaces of the half connectors. These markings can include texture features, color-coding and/or text labels, such as labels 70.” See, col. 5, lines 41-45.

However, there is no intuitive guidance proposed to ensure recognition. Recognition is only gained by learning the shape or color coding, or by reading the labels. In contrast, the present invention employs affordance that guides the user subconsciously and consciously to correct recognition. As used herein the term “application affordance” suggests appropriate usage. The purpose of application affordance is not just to inform the user of the opportunity of making a successful or unsuccessful connection, but also to remind the user of the kind of system he is attempting to connect. Thus, it is not merely a question of, for example, trying to fit a square peg in a round hole, but perhaps more importantly trying to fit a neuraxial connector intended for spinal applications into a respiratory system. The appropriate key should prevent this from happening. However, the visual and tactile cues also serve to prevent attempts from being made to overcome the mechanical keys (such as by over wrapping with flexible tape, to act as a conduit) and to draw attention to the attempted misconnection. Segal et al. fail to teach or suggest application affordance as claimed.

As explained in paragraphs 20 to 22, the claimed application affordance is highly advantageous, because it prevents not only misconnections, but the lost time and effort associated with attempted misconnections. Moreover, the application affordance comprises tactile cues, thereby allowing for connections to be made blind, such as under the sheets of a hospital bed. Accordingly, Applicants respectfully submit that claim 1 is patentable over Segal et al.

Claims 2 to 31 depend from claim 1 and by definition contain all of the limitations of claim 1. Accordingly, Applicant respectfully submits that claims 2 to 23 are patentable over Segal et al. for the reasons given above for claim 1 as well as because of the additional limitations contained therein.

For example, claim 2 further recites “wherein said application affordance comprises a

shape of the grip that is suggestive of a part of a human body for which the application is intended.” The Examiner states that Segal et al. teach this limitation in col. 8, lines 33 to 49.

The portion cited by the Examiner is reproduced below for convenience:

The foregoing safety medical connectors are designed to be interposed between existing devices for medical infusions, injections, or aspirations. An additional feature of the present invention is the fusion of a half connector as illustrated in FIG. 1 into a standard medical connector or device. FIGS. 7A through 7D illustrate the incorporation of a safety connector half into an epidural catheter connector 500, which in turn is connected to an epidural catheter 505. Any of the mating and locking configurations of the present invention, for example the rectangular surface feature 510, can be incorporated into the end of the epidural catheter connector. The epidural catheter connector in turn mates with a complementary safety connector half 520. This connector half includes a complementary shaped surface feature that ensures that only medications intended for epidural delivery are injected through the epidural catheter, since only a specific surface feature 510 can mate with the connector half 520.

Applicants respectfully submit that neither the portion cited by the Examiner, nor the remainder of Segal et al. teach or suggest “a shape of the grip that is suggestive of a part of a human body for which the application is intended” as claimed.

Claim 3 further recites “wherein a first application is neuraxial, and said shape of the grip is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs.” One embodiment of such a grip shape is shown in Fig. 5a. The Examiner cites to the portion reproduced above, col. 8, lines 33 to 49 and to Fig. 7A for teaching this limitation. Applicants respectfully submit that neither the portion cited by the Examiner, nor the remainder of Segal et al. teach or suggest the above limitation. A review of Fig. 7A reveals a cylindrical grip having an indented portion. Applicants respectfully submit that the grip shown in Fig. 7A is not suggestive of a human spine and ribs as claimed.

Claim 4 further recites, “wherein a second application is respiratory, and said shape of the grip is generally cylindrical having alternating frusto-conical sections suggestive of a bellows.” Claim 5 further recites “wherein a third application is enteral, and said shape of the grip is generally cylindrical with bulges down its length suggestive of the human colon.” In rejecting both claims 4 and 5, the Examiner cites to Figures 5 and 7, col. 6, lines 37 to 64, and column 8,

lines 33 to 49. Applicants respectfully submit that neither the portions cited by the Examiner, nor the remainder of Segal et al. teach or suggest the above limitations of claims 4 and 5.

Affordance is more than a label presenting information, because the nature of affordance is that it leads the user to the appropriate action, much as a doorplate invites a user to push the door or a handle invites a user to pull without any requirement for labels saying “push” or “pull”. As explained in paragraphs 78 and 79, components according to embodiments of the present invention can have mechanical affordance such as large wings to emphasize a twisting requirement to effect secure connection, or a button indicating a locking function, actuable by pressing the button.

Claim 8 further recites, “wherein said method of interconnection comprises a twisting step; and wherein said mechanism affordance comprises a wing of said grip.” Claim 9 further recites, “wherein said method of interconnection comprises a pushing step; and wherein said mechanism affordance comprises a waist of said grip.” Claim 10 further recites, “wherein said method of interconnection comprises a locking step; and wherein said mechanism affordance comprises a button of said grip.” The Examiner cites the same elements of Segal et al., namely Figure 2, elements 29 and 35 as teaching all of the limitations of claims 8, 9, and 10. Applicants respectfully submit that elements 29 and 35 are not wings, a waist or a button, and therefore fail to teach or suggest the above limitations of claims 8 to 10. Moreover, Applicants submit that the rejection is improper as citing the same elements for teaching three different structures.

Despite rejecting all of claims 1 to 31 under 35 U.S.C. §102(b), the Examiner did not provide any explanation for the rejection of claims 17 and 28 to 30. Therefore, Applicants submit that the Examiner’s 35 U.S.C. §102(b) rejection of claims 17 and 28 to 30 is improper.

Accordingly, Applicants respectfully request that the rejection of claims 1 to 31 under 35 U.S.C. §102(b) be withdrawn.

### **Rejections Under 35 U.S.C. §103(a)**

The Examiner rejected claims 17 and 28 to 30 under 35 U.S.C. §103(a) as being unpatentable over Segal et al. (U.S. Patent No. 6,402,207 in view of Moberg et al. (U.S. Patent

No. 6,659,980). Applicants respectfully traverse this rejection.

Claims 17 and 28 to 30 depend from claim 1 and by definition contain all of the limitations of claim 1. As explained above with regard to claim 1, Applicants respectfully submit that Segal et al. fail to teach or suggest wherein “said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues.” Applicants respectfully submit that Moberg et al. fail to remedy the defects of Segal et al.

Moberg is directed to improvements in infusion pumps. The Examiner cites to Moberg et al. for teaching ultrasonic welding and adhesion. However, Applicants respectfully submit that Moberg et al. fail to teach or suggest wherein “said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues.”

Accordingly, Applicants respectfully submit that claim 1 is patentable over Segal et al. and Moberg et al., both alone and in combination. Applicants further submit that claims 17 and 28 to 30 are patentable over Segal et al. and Moberg et al. for the reasons given above for claim 1 as well as because of the additional limitations contained therein.

Accordingly, Applicants respectfully request that the rejection of claims 17 and 28 to 30 under 35 U.S.C. §103(a) be withdrawn.

### **CONCLUSION**

Applicants believe that all pending claims are in condition for allowance and such action is earnestly requested. If the present remarks do not place the application in condition for allowance, then the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicants’ representative.

A fee of \$510 for a three month extension of time is believed due with this communication. The Commissioner is hereby authorized to charge payment of this fee and any other fees due with this communication to Deposit Account No. 19-2090.

Respectfully Submitted,

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